General Electric Company
P.O. Box 414, Milwaukee, WI 53201

510(K) SUMMARY

K012875

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.92(c).

Submitter: GE Medical Systems
PO Box 414
Milwaukee, WI 53201

Contact Person: Larry A. Kroger Ph.D.
Manager, Regulatory Programs

Telephone: 262- 544-3894

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Date Prepared: August 23, 2001

Device Name:

GE Signa OpenSpeed Magnetic Resonance System
Magnetic Resonance Diagnostic System, 21 CFR 892.1000, 90-LNH

Marketed Device:

The Signa OpenSpeed Magnetic Resonance System is substantially equivalent to the currently marketed Signa HFO/i Magnetic Resonance System (K992746) with the main differences being an increase in gradient strength from 15mT/m to 25mT/m, and an increase in slew rate from SR25 to SR40. In addition, Diffusion imaging is now offered as an imaging option.

Device Description:

The Signa OpenSpeed Magnetic Resonance System is a modification to the Signa HFO/i Magnetic Resonance System (K992746) which utilizes a superconducting magnet to acquire 2D single-slice and multi-slice, and 3D volume images. The Signa OpenSpeed Magnetic Resonance System is an open style magnet operating at 0.7T. The system can image in the sagittal, coronal, axial, oblique and double oblique planes, using various pulse sequences. Images are acquired and reconstructed using 2D and 3D Fourier transformation techniques. The system is intended for high resolution anatomical applications and shorter scan times. Previously cleared software options, coils, and other accessories may be used with the Signa OpenSpeed Magnetic Resonance System.

Indications for Use:

The Signa OpenSpeed Magnetic Resonance System is an open, whole body scanner designed to support improved higher resolution imaging and shorter scan times. The Signa OpenSpeed Magnetic Resonance System is indicated for use as a diagnostic imaging device to produce transverse, sagittal, coronal and oblique images of the internal structures and organs of the entire body, including, but not limited to, the musculocskeletal, vascular, cardiac, and neuro systems. The images produced by the Signa OpenSpeed Magnetic Resonance System reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. The NMR properties that determine the image appearance are proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2) and flow. When interpreted by a trained

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physician, these images provide information that can be useful in determining a diagnosis.

Due to the 'open' design of the system, the Signa OpenSpeed may also be used for imaging during interventional procedures when performed with MR compatible devices such as, in-room display and MR safe biopsy needles.

Comparison with Predicate Device:

The Signa OpenSpeed Magnetic Resonance System is a modification of the Signa HFO/i MR system (K992746) with the main differences being an increase in gradient strength from 15mT/m to 25mT/m, and an increase in slew rate from SR25 to SR40. In addition, Diffusion imaging is now offered as an imaging option.

Summary of Studies:

The Signa OpenSpeed Magnetic Resonance System was evaluated to the appropriate NEMA performance standards as well as the IEC 601-1 International Medical Equipment Safety standard and IEC 601-2-33 Particular Requirements for Safety of Magnetic Resonance Equipment for Medical Diagnosis. The Signa OpenSpeed Magnetic Resonance System is comparable to the currently marketed Signa HFO/i Magnetic Resonance System.

Conclusion:

It is the opinion of GE that the Signa OpenSpeed Magnetic Resonance System is substantially equivalent to the Signa HFO/i Magnetic Resonance System. The Signa OpenSpeed Magnetic Resonance System does not include any new indications for use, nor does use of this device result in any new potential hazards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 0 2001

Larry Kroger, Ph.D.
Regulatory Programs Manager
GE Medical Systems
General Electric Company
P.O. Box 414
MILWAUKEE WI 53201

Re: K012875
Trade/Device Name: Signa OpenSpeed Magnetic Resonance System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 LNH
Dated: August 23, 2001
Received: August 27, 2001

Dear Dr. Kroger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosures

NOV 2 0 2001

510(k) Number (if known): K012875

Device Name: Signa OpenSpeed Magnetic Resonance System

Indications For Use:

The Signa OpenSpeed Magnetic Resonance System is an open, whole body scanner designed to support improved higher resolution imaging and shorter scan times. The Signa OpenSpeed Magnetic Resonance System is indicated for use as a diagnostic imaging device to produce transverse, sagittal, coronal and oblique images of the internal structures and organs of the entire body, including, but not limited to, the musculocskeletal, vascular, cardiac, and neuro systems. The images produced by the Signa OpenSpeed Magnetic Resonance System reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. The NMR properties that determine the image appearance are proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2) and flow. When interpreted by a trained physician, these images provide information that can be useful in determining a diagnosis.

Due to the 'open' design of the system, the Signa OpenSpeed may also be used for imaging during interventional procedures when performed with MR compatible devices such as, in-room display and MR safe biopsy needles.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Nancy C. Brogdon

Division Sign-Off
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K012875